

DATE: 27/FEB/2001

*Review also applies to
70829-G since both products
use same 'unregistered' source of
glyphosate.*

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: A TECHNICAL GRADE OF ACTIVE INGREDIENT
BARCODE No.: 272447 EPA RECEIVED DATE: 06/DEC/2000 REG./File Symbol No.: 70829-E
PRODUCT NAME: Clearout 41, 41 % glyphosate, isopropylamine MRID.: 448831-19 & 452798-01
COMPANY NAME: Chemical Products Technologies Action Code: 166



FROM: Sami Malak, Chemist *Sami Malak*
Technical Review Branch/RD (7505C)

TO: 25 Jim Tompkins/James Stone
Herbicide Branch/RD (7505C)

INTRODUCTION:

With this re-submission, product's management team 25 requested TRB, for the third time, to re-evaluate this action for a "me-too" registration as per the regulations of FIFRA sec. 3(c)(3)(B)(i)(I). The product manager included two CSFs apparently for comparison if subject product is similar to either one. These are: glyphosate technical, Reg. No. 4787-26, a basic formulation CSF dated 20/APR/1995, and glyphosate, Reg. No. 524-420, an alternate formulation CSF dated 13/FEB/1991. This action was previously reviewed by TRB (Shyam Mathur, 06/NOV/2000 and Bruce Kitchens 16/JAN/2001). In his memorandum, Shyam Mathur requested preliminary analysis data on a non-registered glyphosate acid used in the manufacture of subject product. This data is reviewed in Confidential Appendix A. In addition, the PM requested a clarification of conclusion #3 in the 16/JAN/2000 memorandum regarding a waiver request for some data. In the same memorandum, it was apparent that the product manager had asked for a "me-too" registration claiming similarity of subject product to Roundup Herbicide, Reg. No. 524-445. This was confirmed by the applicant in a phone communication on 20/FEB/2000 (770-606-8166) because Form 8570-1 was not included with this submission. This request was denied because of the differences in the impurity profile (B. Kitchens, 16/JAN/2001). It was noted that the company had chosen the cite-all method of support. Product's CSF, a basic formulation dated 24/JAN/2000 was included with this submission, whereas, product's label was previously reviewed and found adequate (B. Kitchens, 16/JAN/2001).

FINDINGS:

1. The subject product is produced by an integrated production system meaning that the technical source, glyphosate acid, used in the manufacture of subject product is not registered. This glyphosate acid, supplied by 

- 2a. A comparison against product's composition as detailed in the submitted CSF dated 24/JAN/2000, indicated that Clearout 41 %, Reg. No. 70829-e, is not substantially similar to glyphosate technical, Reg. No. 4787-26, a basic formulation CSF dated 20/APR/1995,

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

20/APR/1995, or glyphosate, Reg. No. 524-420, an alternate formulation CSF dated 13/FEB/1991. The subject product contains 30.4% glyphosate acid equivalent to 41.0% glyphosate isopropylamine salt; whereas glyphosate technical, Reg. No. 4787-26 contains 98.3% glyphosate acid and that of glyphosate, Reg. No. 524-420 contains 96.3% glyphosate acid.

* 2b.

The non-registered glyphosate acid, [REDACTED] pure, is substantially similar to glyphosate technical, Reg. No. 4787-26, 98.3% pure, a basic formulation CSF dated 20/APR/1995. It is also similar to glyphosate Reg. No. 524-420, 96.3% pure, an alternate formulation CSF dated 13/FEB/1991.

3. As per the applicant's request, a similar comparison was made relative to Roundup Herbicide, Reg. No. 524-445 (phone communication on 20/FEB/2001), revealed that both products are substantially similar. The nominal concentration of 41% glyphosate isopropylamine salt is the same in both products. The upper and lower certified limits in both products are within the standard certified limits of 40 CFR § 158.175(b)(2). Because subject product was produced by an [REDACTED] and the referenced product, Reg. No. 524-445, was formulated, using isopropylamine salt of glyphosate, Reg. No. 524-333, it is not anticipated that the composition would be the same. In subject product two impurities were listed including sodium chloride not found in Reg. No. 524-445. On the other hand, both products are water-base, each containing not less than [REDACTED] resulted from the [REDACTED] in subject product and intentionally added in Reg. No. 524-445.
- 4a. Previously submitted data in MRIDs 451929-02 & 451929-03 satisfied the requirements for nitrosamine analysis, storage stability, and corrosion characteristics (B. Kitchens, 16/JAN/2001).
- 4b. The remaining product chemistry data requirements to support registration of subject product, isopropylamine salt of glyphosate, was previously submitted and found adequate (MRIDs 448831-01, 448831-02 & 448831-03).
- 5a. The submitted product chemistry data in MRID #452798-01 pertaining to identity, manufacturing, and impurities in the non-registered glyphosate acid corresponding to OPPTS GRNs 830.1550, 830.1600, 830.1620 and 830.1670, was previously reviewed and found adequate (Bruce Kitchens, 16/JAN/2001).
- 5b. The submitted product chemistry data in MRID #452798-01 pertaining to preliminary analysis and certification of limits for the ingredients found in the non-registered glyphosate acid, summarized in Confidential Appendix A, satisfies the requirements of 40CFR§158.170 and OPPTS GRN 830.1700.
- 5c. Based on Finding 2(b) above, the waiver request for certain physical/chemical properties

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

is acceptable. These are: dissociation constant (GRN 830.7370), partition coefficient (GRN 830.7550), water solubility (GRN 830.7840), and vapor pressure (GRN 830.7950). This should address Conclusion 3 of the 16/JAN/2001 memorandum. These properties are generated using pure glyphosate acid and under the cite-all method of support, they can be satisfied by data from any pure glyphosate acid such as the one in Reg. No. 524-445.

- 5d. To summarize, adequate data is available to support the use of the non-registered glyphosate acid to formulate subject product: Reviews by S. Mathur, 06/NOV/2000, B. Kitchens, 16/JAN/2001, data reviewed in this memorandum pertaining to its composition, and referenced data (Data Matrix, and the applicant's FAX to this reviewer dated 21/FEB/2001).

6. The analytical method that can be used for the determination of glyphosate acid in subject product is based on the following publication: Morlier, L. W. and Tomkins, D. F., "Liquid Chromatography Determination of Glyphosate in Water-Soluble Granular Formulations: Collaborative Study," Journal of AOAC International, 80(3):464-468 (1977). Source: MRID #448831-19. The method is equipped with a UV detector. Modifications were made to this method in the analyses presented in this submission whereby the pH of the mobile phase was adjusted to 1.9 and the sample size was adjusted from 0.4 g to 0.1 g. The impurities were determined by using an Ion Chromatography method (HPLC equipped with a conductivity detector). The chloride and phosphate were also detected. The chloride was assumed to be present as sodium chloride. The phosphate was assumed to be present as disodium hydrogen phosphate. Aminomethyl phosphonic acid (AMPA) was determined by HPLC method utilizing post-column derivatization and fluorescence detection. Methods validation regarding accuracy, precision, recovery data and linearity are adequate. Sample calculations and chromatograms were included with this submission.

The published and validated analytical method for the determination of glyphosate acid exempts the applicant from submitting samples (GRN 830.1900) of the non-registered glyphosate acid and seeking method validation by EPA's laboratory in Fort Meade, Maryland.

7. The [REDACTED] reactants used to produce the non-registered glyphosate should be identified as such, i.e. "reactants" on product's CSF instead of "active ingredients."
8. Lower certified limits for impurities requested in connection with the 16/JAN2001 memorandum are not required as per the regulations of OPPTS Test Guidelines, Series 830.
9. Under the cite-all method of support, an applicant is not obliged to list specific studies or data owners. The applicant had correctly followed the regulations of 40CFR§152.95.

CONCLUSIONS:

1. From the product chemistry point of view, Clearout 41%, Reg. No. 70829-e, is substantially similar to Roundup Herbicide, Reg. No. 524-445.
2. The non-registered glyphosate acid, [REDACTED] pure, is substantially similar to glyphosate technical, Reg. No. 4787-26, 98.3% pure, a basic formulation CSF dated 20/APR/1995. It is also similar to glyphosate Reg. No. 524-420, 96.3% pure, an alternate formulation CSF dated 13/FEB/1991.
3. The applicant should be advised to address Finding 7 above.

GRN 830-1800 Enforcement Analytical Methods:

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70829-3

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The material not included contains the following type of information:

- _____ Identity of product inert ingredients.
- _____ Identity of product impurities.
- ☒ Description of the product manufacturing process.
- _____ Description of quality control procedures.
- _____ Identity of the source of product ingredients.
- _____ Sales or other commercial/financial information.
- _____ A draft product label.
- _____ The product confidential statement of formula.
- _____ Information about a pending registration action.
- _____ FIFRA registration data.
- _____ The document is a duplicate of page(s) _____.
- _____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.